

# PATENT COOPERATION TREATY

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To:

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## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2005/000926

International filing date (day/month/year)  
10.03.2005

Priority date (day/month/year)  
10.03.2004

International Patent Classification (IPC) or both national classification and IPC  
A61M15/00

Applicant  
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000926

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material:  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing:  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000926

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 155-157

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 155-157
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000926

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**Box No. IV Lack of unity of invention**

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1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos.

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	7, 12, 14-16, 18-25, 28-31, 34-42, 53, 55, 59, 63-68, 85-87, 105, 134-154
	No: Claims	1-6, 8-11, 13, 17, 26, 27, 32, 33, 43-52, 54, 56, 57, 58, 60-62, 69-84, 88-104, 106-133
Inventive step (IS)	Yes: Claims	7, 14-16, 53, 55, 59, 63-68
	No: Claims	1-6, 8-13, 17-52, 54, 56, 57, 58, 60-62, 69-154
Industrial applicability (IA)	Yes: Claims	1-154
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item III.**

Claims 155-157 are referring solely on the figures, and do not have any technical features as such. Therefore no meaningful search can be carried out for said claims (Article 6 PCT).

**Re Item IV.**

The separate inventions/groups of inventions are:

1. Claims 1-42, 72-78 An inhaler with a closure having a restricting member for preventing unintentional actuation of the inhaler.
2. Claims 43-51, 89-91 Inhaler with a housing and a closure with an extendible connector part.
3. Claims 52-61 An inhaler with a restricting member fastened to the canister unit.
4. Claims 62-70 An inhaler with a restricting member which is inserted between the dispensing member and the housing.
5. Claims 71 An inhaler with a restricting means which restricts movement between the dispensing member and the housing and prevents removal of the dispensing member from the housing.
6. Claims 79-88 An accessory for use with an inhaler, the accessory having a restricting member for preventing dispensing the dose when attached to the inhaler.
7. Claims 92-95 A connector for connecting an accessory to an inhaler, the connector having a restricting member.
8. Claims 96-133 A dispensing device with a housing and a closure comprising a cap and a feature for insuring correct orientation of the closure to the user

and a closure with a cap having an extension for engaging a dispensing device and indicating incorrect orientation of the cap on the device..

9.Claims 134-154     A dust cap for a pMDI with a strap part, the cap being slidable on the strap part.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The independent claims 1,43,52,62,71,72,79,89,92,96,112 and 134 have no special common features which are novel inventive over US-3622053, therefore said claims lack clarity within the sense of Rule 13 PCT. Said claims or group of claims address different problems or even relate to different objects.

Claims 1-42 and 72-78 relate to an inhaler with a closure having a restricting member in order to avoid accidental actuation. The subject-matter of claim 1 is not novel in view of the device of US-3622053, and an objection of lack of unity a posteriori for many of the dependent claims 2-42 could have been raised. Nevertheless, they have been searched in together with the subject-matter of claim 1 as far as reasonable.

Claim 89-91 relate to a closure with an extendible connector part and claim 43-51 relate to an inhaler with a such closure in order to facilitate connection between the closure and the housing without any restricting member.

Claims 52-61 relate to an inhaler with a restricting means which is fastened to the canister (said feature cannot be seen as unitary with the restricting member of claim 1, because it is not ).

Claims 62-70 relate to an inhaler with a restricting means which is inserted between the dispensing member and the housing (said feature cannot be seen as unitary with the restricting member of claim 1 or 52, a restricting member as such being known from US3622053, the various realisations relate to different problems and are not linked by a common concept).

Claims 71 relate to an inhaler with a restricting means which also prevents removal of the canister (fig.14a and b, effect which is not achieved by any of the other embodiments thus linked to a different problem of avoiding accidental removal of the canister)



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2005/000926

Claims 79-88 relate to an accessory for use with an inhaler which is releasably attached to the inhaler and is thus a priori not unitary with the subject-matter of the preceding independent claims (different own entity)

Claims 92-95 relate to connector with a restricting member for connecting an accessory to an inhaler (also a separate entity).

Claims 96-111 relate to a dispensing device with a closure/housing arrangement for avoiding wrong orientation of the closure on the housing (the common feature with the other independent claims are also known from US3622053) and claims 112-133 to A closure with a cap having an extension for engaging a dispensing device and indicating incorrect orientation of the cap on the device.

Claims 134-154 relate to a dust cap for a pMDI with a strap part, the cap being slidable on the strap part (apart from the cap and the connecting means (strap) no novel or inventive common features with the other independent claims).

**Re Item V.**

Reference is made to the following documents:

- D1 : US 3 622 053 A (JOHN V. RYDEN) 23 November 1971 (1971-11-23)
- D2 : US 3 927 806 A (MESHBERG ET AL) 23 December 1975 (1975-12-23)
- D3 : GB-A-1 044 627 (BENGER LABORATORIES LIMITED) 5 October 1966
- D4 : US-A-3 191 867 (HELMS W. LEE) 29 June 1965 (1965-06-29)
- D5 : GB-A-2 364 320 (BESPAK PLC) 23 January 2002 (2002-01-23)
- D6 : US-A-5 899 200 (MCNARY ET AL) 4 May 1999 (1999-05-04)
- D7 : DE 298 18 662 U1 (JOSEF WISCHERATH GMBH & CO. KG) 2 March 2000
- D8 : US-A-4 940 051 (LANKINEN ET AL) 10 July 1990 (1990-07-10)
- D9 : WO 2004/064906 A (LANGFORD, STANLEY, C) 5 August 2004 (2004-08-05)
- D10 : US-A-4 641 644 (ANDERSSON ET AL) 10 February 1987 (1987-02-10)
- D11 : WO 99/38555 A (GOLDSTEIN & LEWIN TECHNOLOGY GMBH;  
GOLDEMANN, RAUL; SCHWARZWALD, DETLE) 5 August 1999
- D12 : WO 2004/089782 A (S. C. JOHNSON & SON, INC; FURNER, PAUL, E;  
NELSON, CORY, J) 21 October 2004 (2004-10-21)
- D13 : WO 2005/046774 A (ASTRAZENECA AB; BUNCE, MARTIN) 26 May 2005
- D14 : US-A-3 549 055 (LAWRENCE O. GATLAND) 22 December 1970

D15: WO 91/06333 A (NOVO NORDISK A/S) 16 May 1991 (1991-05-16)  
D16: US-A-3 826 413 (WARREN W,GB) 30 July 1974 (1974-07-30)  
D17: WO 97/06842 A (PHARMASOL LIMITED; OPPERMAN, NICHOLAS,  
RICHARD, JAMES) 27 February 1997 (1997-02-27)

**V.I. Claims 1-42,72-78     An inhaler with a closure having a restricting member for preventing unintentional actuation of the inhaler.**

**I.1     INDEPENDENT CLAIM 1**

I.1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):  
An inhaler (fig.2) for use with a container unit containing a medicament formulation to be dispensed, comprising: a housing (12, fig.2) in which the container unit (2, fig.2) is relatively movable thereto to cause dispensing of a dose, preferably a metered dose, of the medicament formulation from the container unit for inhalation by a user through a dispensing outlet of the housing (fig.2);  
a closure (40, fig.2) positionable to close the dispensing outlet; and  
a restricting member (44, fig.2) , provided on the closure, movable between a first position which enables relative movement between the container unit and the housing for dispensing of the dose of the medicament formulation, and a second position in which the restricting member restricts relative movement between the container unit and the housing such that dispensing of the dose of the medicament formulation is prevented (see fig.2 and col.3 lines 20-24);  
wherein when the closure is positioned to close the dispensing outlet, the restricting member enters the housing through the dispensing outlet to be disposed in its second position (as seen on fig.2 the end of wall 42 is outside of the housing (dashed lines) in the dispensing position and when the hood 40 is pivoted to close the dispensing aperture, the wall end portion 44 enters the housing and is in position for blocking actuation of the canister ).

I.1.2 The subject-matter of claim 1 does not appear to be novel either in view of the device of D3 (see fig.1 and page 2 left hand column lines 1-19).



**I.2 INDEPENDENT CLAIM 72**

I.2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 72 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

An inhaler (fig.2) comprising: a housing (12, fig.2) in which a medicament formulation is received and a dispensing member (6, fig.2) is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing; and a restricting member (44, fig.2) movable between a first position (dashed line fig.2, item 40) which enables relative movement between the dispensing member and the housing for dispensing of the dose of the medicament formulation, and a second position (full line fig.2, col.3 lines 20-24) in which the restricting member restricts relative movement between the dispensing member and the housing such that dispensing of the dose of the medicament formulation is prevented; wherein the restricting member enters the housing through the dispensing outlet to be disposed in its second position.

I.2.2 The subject-matter of claim 72 does not appear to be novel either in view of the device of D3 (see fig.1 and page 2 left hand column lines 1-19).

**I.3 DEPENDENT CLAIMS**

I.3.1 DEPENDENT CLAIMS 2-6, 8-11, 13, 17, 22-24, 26-28, 30-33, 73-78

Dependent claims 2-6, 8-11, 13, 17, 22-24, 26-28, 30-33, 73-78 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

The features from claims 2-6, 8-11, 13, 17 and 32-33 and 73-78 are also disclosed in D1 (see figures and related passages in the description).

The dose counting means defined in claims 22-24, 26-28 and 30-31 is already known from D2 (see also page 23 last two § of the present application). A skilled person wishing to put a dose counting system in the device of D1 would use the teaching of D2 and thus arrive at the subject-matter of said claims, which thus lacks an inventive step within the sense of Article 33(3) PCT.

**I.3.2 DEPENDENT CLAIMS 12,13,18-21,25,33-42**

In claims 12,13,18-21,33-42 slight constructional changes in the Inhaler of claim 1 are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claims 12,13,18-21,33-42 also lacks an inventive step (Article 33(3) PCT).

**I.4 DEPENDENT CLAIMS 7,14-16**

The subject-matter of claim 7 (and from dependent claims 14-16 when dependent on claim 7) differs from the device of D1 in that the restricting member is a clip for retaining the restricting member in its second position. The subject-matter of said claim does not appear to be obvious in view of the available prior art. Claims 7 and 14-16 when dependent on claim 7 therefore appear to meet the criteria of Article 33(2) and (3) PCT.

- I.5** The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. Moreover, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.

**II. Claims 43-51,89-91 Inhaler with a housing an a closure with an extendible connector part.**

**II.1 INDEPENDENT CLAIM 43**

- II.1.1** The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 43 is not novel in the sense of Article 33(2) PCT. Document D5 discloses (the references in parentheses applying to this document):  
An inhaler comprising a housing having a dispensing outlet (8, fig.1), and a closure (9, fig.1) for closing the dispensing outlet, wherein the closure comprises a connector part (10, fig.2a-c) for connecting the closure to the housing whereby the connector part is extendible (see page 7 line 19).

II.1.2 The subject-matter of claim 43 is also not novel in view of D4 (fig.1), D6 (see fig.8) and D7 (see figs.1-2)

## II.2 INDEPENDENT CLAIM 89

II.2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 43 is not novel in the sense of Article 33(2) PCT. Document D5 discloses (the references in parentheses applying to this document):

A closure (9, fig.1) for use with an inhaler which comprises a housing for receiving therein a medicament formulation for inhalation by a user through a dispensing outlet of the housing, the closure having a closing part for closing the dispensing outlet of the housing and a connector part (10, fig.1 and 2a-2c) for connecting the closure to the housing, the closing part being movable between a closing position (fig.2a), in which it closes the dispensing outlet, and an opening position (fig.2c), in which it opens the dispensing outlet, while the closure is connected to the housing by the connector part, wherein the connector part is extendible between a contracted state and an extended state (see fig.2b and page 7 line 19) to enable the closure part to move between its closing and opening positions, respectively.

## II.3 DEPENDENT CLAIMS 44-51,90,91

II.3.1 The subject-matter of dependent claims 48,49 and 90 is also not novel in view of D5 (cf. strap 10, fig.2a-2c)

II.3.2 The subject-matter of dependent claims 45-47,50-51 is not novel in view of D4 (see figures 1-3, with the sliding closure 4, fig.1, items 7,8 fig.1)

II.3.3 D10 discloses an inhaler device with a telescopic closure connected to the housing (see fig.1 and abstract). Therefore, the subject-matter of claims dependent claims 44 and 91 is not novel either (Article 33(3) PCT). D11 is also novelty destroying for said claims (see figures).

**III. Claims 52-61 An inhaler with a restricting member fastened to the canister unit.**

**III.1 INDEPENDENT CLAIM 52**

III.1.1 The subject-matter of claim 52 does not appear to be novel in view of the device of D17 (fig.1, clip 20, page 5 last §) which teaches the use of a clip in order to prevent actuation of a dispenser (Article 33(2) PCT). Here, the vial (2,fig.1) is considered as a canister.

III.1.2 Document D9 published on 05.08.2004, i.e between the priority and filing date of the present application discloses (the references in parentheses applying to this document):  
An inhaler comprising: a housing (16, fig.1) in which a medicament formulation is received and a dispensing member (18, fig.1) is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet (14, fig.1) of the housing; and a restricting member (10, figs.1-3) adapted to restrict relative movement between the dispensing member and the housing such that dispensing of the dose of the medicament formulation is prevented wherein the restricting member is fastened to the canister unit (see fig.1 and abstract).

III.1.3 D12, published on 21.10.2004 also appears relevant for the novelty of claim 52 (see fig.13, § [44]).

**III.2 DEPENDENT CLAIMS 54,56-58,60**

III.2.1 The subject-matter of claims 54,56-58,60,61 is also not novel in view of document D9 (see figs.1-3).

**III.3 DEPENDENT CLAIMS 53,55,59**

III.3.1 The subject-matter of claims 53, 55 and 59 is not considered to be rendered obvious by the available state of the art (Article 33(3) PCT). No restricting

device fastened to both the canister and the housing, or adhesively fastened to one of the two or through an aperture in the housing was revealed by the search.

**VI. Claims 62-70      An inhaler with a restricting member which is inserted between the dispensing member and the housing.**

**VI.1 INDEPENDENT CLAIM 62**

VI.1.1      In D17, the clip 20 is also inserted between the dispensing member (upper part of fig.1) and the housing (lower part of fig.1), therefore, the subject-matter of claim 62 is not considered to be novel in view of the device disclosed in D17 (Article 33(2) PCT).

VI.1.2      Document D9 published on 05.08.2004, i.e between the priority and filing date of the present application discloses (the references in parentheses applying to this document):  
An inhaler comprising: a housing (16, fig.4) in which a medicament formulation is received and a dispensing member (18, fig.4) is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing; and a restricting member (50, fig.4) which is inserted between the dispensing member and the housing (see fig.4, the cap 50 is inserted between the canister and housing) to restrict the relative movement therebetween such that dispensing of the dose of the medicament formulation is prevented (see page 18 line 12 to page 19 line 7).

VI.1.3      D12, published on 21.10.2004 also appears relevant for the novelty of claim 62 (see fig.13, § [44]).

**VI.2 DEPENDENT CLAIMS 63-70**

VI.2.1      The subject-matter of claims 69 and 70 is also not novel in view of the device of D9 (fig.4).

VI.2.2 The subject-matter of claims 63-68 is not rendered obvious by the available prior art (Article 33(3) PCT). No restricting member in the form of a wedge or made of foam or other elastically compressible material was revealed by the search.

**V.Claim 71      An inhaler with a restricting means which restricts movement between the dispensing member and the housing and prevents removal of the dispensing member from the housing.**

V.1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 71 is not novel in the sense of Article 33(2) PCT. Document D8 discloses (the references in parentheses applying to this document): An inhaler comprising:  
a housing (1, fig.1) in which a medicament formulation is received and a dispensing member (3, fig.1) is relatively movable along an axis of the housing, movement of the dispensing member in a first axial direction causing dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet (11, fig.1) of the housing, and movement in an opposed second axial direction removing the dispensing member from the housing; and  
a restricting member (2, fig.1) which is positioned in the inhaler to restrict relative movement between the dispensing member and the housing along said axis such that dispensing of the dose of the medicament formulation is prevented and removal of the dispensing member from the housing is inhibited or prevented (see col.2 lines 40-43 and col.3 lines 15-19).

**VI. CLAIMS 79-88      An accessory for use with an inhaler, the accessory having a restricting member for preventing dispensing the dose when attached to the inhaler.**

**VI.1 INDEPENDENT CLAIM 79**

VI.1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 79 is not novel in the sense of Article 33(2) PCT. Document D3 discloses (the references in parentheses applying to this



document):

An accessory (cap, fig.2) for use with an inhaler which comprises a housing for receiving therein a medicament formulation and a dispensing member for relative movement therebetween which causes a dose of the medicament formulation to be dispensed for inhalation by a user through a dispensing outlet of the housing, the accessory being adapted to be releasably attached (fig.1) to the inhaler in a use position and having a restricting member (16, fig.1) which, when the accessory is attached to the inhaler in its use position, extends into the housing through the dispensing outlet (fig.1) to restrict the relative movement between the housing and the dispensing member such that dispensing of the dose is prevented (see page 2 left hand column lines 1-12).

## VI.2 DEPENDENT CLAIMS 80-84,88

- VI.2.1 The subject-matter of claims 80-84 is also not novel in view of the cap of document D3 (see passages cited above).
- VI.2.2 The subject-matter of claim 85-87 does not appear to involve an inventive step in view of D3 and D17 (article 33(3) PCT).
- VI.2.3 The subject-matter of claim 88 does involve an inventive step over a combination of D3 with the teaching of D5. It would be obvious for the skilled person to provide a strap for connecting the closure of D3 with the housing of the dispenser, so that the closure does not get lost. (Article 33(3) PCT).

## **VII.Claims 92-95      A connector for connecting an accessory to an inhaler, the connector having a restricting member.**

### VII.1 INDEPENDENT CLAIM 92

- VII.1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 92 is not novel in the sense of Article 33(2) PCT. Document D7 discloses (the references in parentheses applying to this

document):

A connector (15,17,18 fig.1) suitable for connecting an accessory ("Kappe" 11, fig.1) to an inhaler housing (2, fig.1) in which a medicament formulation is received and in which a dispensing member is relatively movable to dispense a dose of the medicament formulation for inhalation by a user at a dispensing outlet (3, fig.1) of the housing, wherein the connector comprises a restricting member (9, fig.1, see page 9 § 3) adapted in use to restrict movement of the dispensing member relative to the housing to prevent the dose being dispensed.

## VII.2 DEPENDENT CLAIMS 92-95

VII.2.1 The subject-matter of claims 92-95 is also not novel in view of the device of document D7 (Article 33(2) PCT). Indeed the arm 9 is insertable through an opening in the housing to position in which actuation is inhibited (see fig.1). Moreover, the accessory (Kappe 11, fig.1) is a closure which is carried out by the connector 15,17,18, fig.1 and closes the dispensing outlet in its restricting position.

**VIII. Claims 96-133 A dispensing device with a housing and a closure comprising a cap and a feature for insuring correct orientation of the closure to the user and a closure with a cap having an extension for engaging a dispensing device and indicating incorrect orientation of the cap on the device.**

## VIII.1 INDEPENDENT CLAIM 96

VIII.1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 96 is not novel in the sense of Article 33(2) PCT. Document D15 discloses (the references in parentheses applying to this document):  
A dispensing device (fig.1) for dispensing a substance comprising:  
a housing in which the substance is receivable and which has a dispensing nozzle (46, fig.1) from which the substance is in use dispensed; and a closure (47, fig.1) for releasable mounting on the nozzle for closure thereof; wherein the

closure comprises a cap member (47, fig.1) which is configured and arranged with respect to the nozzle such as to be capable of being slid over the nozzle in an intended orientation (fig.1) of the cap member and an unintended orientation of the cap member (the cap being asymmetric, one can try to mount the cap on the nozzle in a wrong orientation);

wherein in the intended orientation of the cap member the closure is securably mounted on the nozzle by sliding the cap member over the nozzle by a predetermined amount to a stationary position (fig.1); and

wherein the housing and the closure are configured and arranged with respect to each other such that the cap member cannot slide over the nozzle by the predetermined amount to a stationary position when in the unintended orientation thereby to indicate to the user that the closure is not correctly mounted on the nozzle (if the cap in D15 is mounted in wrong way, due to the asymmetry of the cap, the cap cannot be inserted fully, this is evident from fig.1). The subject-matter of claim 96 is also not novel in view of D14 (see fig.1, cap 16 asymmetric and having projections 17) and D16 (fig.1, tongue 32a of the cap 32) which both discloses caps which are asymmetric and which can thus be inserted only in a given orientation and directly give an indication to the user if he tries to insert the cap with a wrong orientation.

## VIII.2 DEPENDENT CLAIMS 97-111

VIII.2.1 The subject-matter of claims 97-103 does not appear to be novel in view of documents D14-D16 (see especially the figures) or relate to minor design changes which fall into normal practice for a skilled person (Article 33(2) and (3) PCT). Moreover D14 discloses a cap with projections 17 which act as restricting members in order to prevent inadvertent actuation (cf, fig.1 and col.3 lines 35-40), such that the subject-matter of claims 104 and 106-111 is also not novel (Article 33(2) PCT). The subject-matter of claim 105 does not appear inventive in view of a combination D3 with one D14-D16. Indeed, the skilled person wanting to alert the user in D3 that the cap may be inserted in the wrong way would use an asymmetric cap or keying prongs in order to solve said problem thus arriving at the subject-matter of claim 105.

### VIII.3 INDEPENDENT CLAIM 112

VIII.3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 96 is not novel in the sense of Article 33(2) PCT. Document D14 discloses (the references in parentheses applying to this document):

A closure (16, fig.1) for closing a dispensing nozzle of a dispensing device, the closure having:

a cap (16, fig.1) adapted in use to be securably mounted on the nozzle by insertion of the nozzle into the cap a predetermined amount when the cap is in an intended orientation (fig.2), and

an extension (17, fig.1) for engaging the dispensing device when an attempt is made to insert the nozzle into the cap in an unintended orientation thereof, the extension being configured and arranged such that it engages the dispensing device before the nozzle is able to be inserted into the cap by the predetermined amount when the cap is in the unintended orientation, thereby to indicate that the closure is not being correctly mounted on the nozzle (the cap being asymmetric, is the user tries to insert the cap in a wrong orientation, either the projections 17, fig.1 or the inclined portion of the cap will abut the part 7, fig.1 or the housing 12, fig.1, thus indicating to the user that the cap is not inserted properly).

The subject-matter of claim 112 does not appear to be novel in view of D15 and D16 either (see especially the figures).

### VIII.4 DEPENDENT CLAIMS 113-133

VIII.4.1 The subject-matter of claims 113-133 is either known from D14-D16 or appears to relate to normal design measures for a skilled person in the field of inhalers. Various connecting means are disclosed in D4-D6 and D11. A restricting member inserted through the nozzle in use is known from D3. Therefore the subject-matter of claims 113-133 does not appear to fulfill the requirements of Articles 33(2) or (3) PCT.

**IX. Claims 134-154 A dust cap for a pMDI with a strap part, the cap being slidable on the strap part.**

**IX.1 INDEPENDENT CLAIM 134**

IX.1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 134 is not inventive in the sense of Article 33(3) PCT.

Document D6 discloses (the references in parentheses applying to this document):

A dust cap (12, fig.6) for a pMDI (4, fig.6) having a cap part (fig.6) adapted for a push-fit on the dispensing nozzle of the pMDI and a strap part (10, fig.6) for connecting the dust cap to the pMDI, wherein the cap part is mounted on the strap part for movement between an extended position (fig.6) and a contracted position (fig.8).

IX.1.2 The subject-matter of claim 134 differs from the device of D6 in that the cap part is slidably mounted on the strap part.

IX.1.3 However, these features have already been employed for the same purpose in a similar inhaler, see document D11, page 8, lines 8-22. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to an inhaler according to document D6, thereby arriving at an Inhaler according to claim 134.

IX.1.4 Document D13, published on 26.05.2005 and claiming priority of 17.11.2003, is also relevant to the novelty of claims 134-154, see especially the figures.

**IX.2 DEPENDENT CLAIMS 135-154**

IX.2.1 The features of dependent claims 135-154 are either known from D6 or D11, or relate to obvious design measures for a skilled person in the field of inhalers. Therefore the subject-matter of claims 135-154 does not involve an inventive step within the sense of Article 33(3) PCT either.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

**PCT/GB2005/000926**

- X. The closest prior arts for the various inventions above have not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. Moreover, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.